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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,511	12/05/2003	Juha Voipio	3501-1077	7857

466 7590 10/23/2007  
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EXAMINER
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MALAMUD, DEBORAH LESLIE

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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10/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/727,511	Applicant(s) VOIPPIO ET AL.	
	Examiner Deborah Malamud	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 7 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The examiner acknowledges the amendments received 07 August 2007. Claims 8-13 are cancelled; claims 1-7 are pending.

### ***Claim Objections***

2. In view of the amendments to the claims, the examiner withdraws the objection to claim 7.
3. However, claim 1 is objected to because of the following informalities: the examiner suggests inserting the word "wherein" directly after "parameters," in line 7 of the claim. Appropriate correction is required.

### ***Response to Arguments***

4. Applicant's arguments filed 07 August 2007 have been fully considered but they are not persuasive. The applicant argues (page 6, "Remarks") "In contrast [to Zabara, a previously cited reference], as set forth above, the VNS stimulation is provided and any change in parameters such as respiratory changes are used to indicate that an adequate level of VNS stimulation is achieved. The respiratory changes are induced by VNS and are not symptoms of the disease/disorder attempted to be treated." The examiner respectfully disagrees that Zabara does not do this. In col. 5, lines 46-65, Zabara discusses the importance of "tuning" current parameters of a stimulation signal in order to produce a desired clinical effect. Zabara also discloses a "sensor-feedback system" in col. 6, lines 39-63 and in Figure 3, which includes a feedback loop for

evaluating stimulation parameters' efficacy in abating a medical condition. Either of these systems satisfy the claimed requirements for sensing respiratory changes induced by stimulation, in order to determine a stimulation regime that is optimal for a patient with a medical condition.

5. The applicant further argues (pages 6-7, "Remarks") "KING [previously cited reference]...uses changes in, for example, respiration to activate VNS. In KING, an interruption of respiration, or the consequent increase in blood  $P_{CO_2}$ , are characteristic symptoms of apnea. KING uses such changes as an indication to activate VNS, such that the symptoms of the disorder (apnea) control the VNS. In contrast, as set forth above, the VNS stimulation is provided and any change in parameters such as respiratory changes are used to indicate that an adequate level of VNS stimulation is achieved. The respiratory changes are induced by VNS and are not symptoms of the disease/disorder attempted to be treated." Again, the examiner notes that King (par. 0009) teaches that information relating to identified apneas or arousals can be used "as feedback for adjusting characteristics of neurostimulation, e.g., amplitude, for subsequent delivery of neurostimulation in response to a detected apnea or associated arousal." It is also to be noted that a sensor that senses information relating to a medical condition while it is administering a treatment necessarily monitors the effect of the treatment. Therefore, changes in the treatment due to monitored effects of the treatment being administered constitutes the claimed requirement of monitoring the changes in parameter values which are induced by changes in the VNS intensity.

6. Applicant's arguments with respect to claim 4 have been fully considered and are persuasive. The objection to claim 4 has been withdrawn.

***Claim Rejections - 35 USC § 102***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Zabara et al (U.S. 4,702,254); and claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al (U.S. 2004/0210261). For a full discussion of the claim elements, please see above and the previous Non-Final Office Action.

***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zabara et al (U.S. 4,702,254) or King et al (U.S. 2004/0210261). For a full discussion of the claim elements, please see above and the previous Non-Final Office Action.

***Allowable Subject Matter***

11. Claims 4 and 7 are allowed.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
CARL LAYNO  
PRIMARY EXAMINER

  
Deborah L. Malamud  
Patent Examiner  
Art Unit 3766